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*H. N.*

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/235,416 01/22/99 SAKOWICZ

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020350 HM22/0619  
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EXAMINER

NAVARRO, A

ART UNIT

PAPER NUMBER

1645

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DATE MAILED:

06/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/235,416

Applicant(s)

Sakowicz et al

Examiner

Mark Navarro

Group Art Unit

1645



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-58 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-58 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13 and 49-56, drawn to DNA, classified in class 536, subclass 23.1.
  - II. Claims 14-22, drawn to proteins, classified in class 530, subclass 350.
  - III. Claims 23-28, drawn to an antibody, classified in class 530, subclass 387.1.
  - IV. Claims 29-33, drawn to a method of diagnosis, classified in class 435, subclass 7.1.
  - V. Claims 34-46, drawn to a method for screening modulators, classified in class 435, subclass 7.4.
  - VI. Claims 47-48, drawn to a computer system method.
  - VII. Claim 57, drawn to a method for identifying sequence changes.
  - VIII. Claim 58, drawn to a method for identifying agents which binds TL- $\gamma$ , classified in class 424, subclass 130.1.

2. The inventions are distinct, each from the other because of the following reasons:

Invention I drawn to a DNA molecule, and Invention II drawn to a polypeptide molecule are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the

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polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention III drawn to an antibody is distinct from Inventions I-II and III-VIII, since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing.

Invention IV, drawn to a method of diagnosis is distinct from Inventions I-III and V-VIII since it requires additional biological reagents and parameters for the detection and correlating the amount of analyte present with disease.

Invention V, drawn to a method of screening modulators, is distinct from Inventions I-IV and VI-VIII, since it requires additional biological reagents for the detection of activity which effects the analyte.

Invention VI, drawn to a computer method is distinct from Inventions I-V and VII-VIII since it requires computer computations.

Invention VII, drawn to a method for identifying sequence changes is distinct from Inventions I-VI and VIII since it requires additional biological reagents or equipment for detecting sequence modifications.

Invention VIII, drawn to a method for identifying agents which bind TL- $\gamma$ , is distinct from Inventions I-VII, since it requires additional biological reagents and equipment for detecting binding.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.



Mark Navarro

Primary Examiner

June 16, 2000